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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/500,144	03/18/2005	Carl Sidonius Maria Andela	12810-00240-US	5241
23416 7590 05/16/2007 CONNOLLY BOVE LODGE & HUTZ, LLP P O BOX 2207 WILMINGTON, DE 19899			EXAMINER HANLEY, SUSAN MARIE	
			ART UNIT 1651	PAPER NUMBER
			MAIL DATE 05/16/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/500,144

Applicant(s)

ANDELA ET AL.

Examiner

Susan Hanley

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 08 March 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2 and 4-26 is/are rejected.
- 7) ☒ Claim(s) 3 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>10/5/04; 11/15/06</u> . | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

Susan Hanley is now the examiner for this application.

Claims 1-26 are pending.

### *Election/Restrictions*

Applicant's election with traverse of Group I, claims 1-12 and 20-25, in the reply filed on 3/8/07 is acknowledged. The traversal is on the ground(s) that DeLima et al. does not disclose the special technical feature because DeLima et al. is directed to an enzyme-containing granulate having a PEG coating. Applicant asserts that PEG is not a polyolefin and presents evidence to show such. Applicant also argues that the method of claim 1 is similar to that of co-pending 10/125,272, wherein DeLima et al. was applied, and that BAPI considered DeLima to be non-obvious and non-anticipatory over the claims in that case. Applicant also argues that the remaining groups are directed to the special technical feature (an enzyme-containing granulate having a polyolefin coating) and should be rejoined. Applicant also asserts that there is no undue burden to the examiner to search all of the groups. With the exception of the argument related to the BAPI decision, the arguments are found persuasive and the groups are rejoined. Regarding the argument that cites the BAPI decision in 10/125,272, each case is examined on its own merits and a BAPI decision in one case may or may not fit the fact pattern of another case, be it co-pending or not.

Claims 1-26 are under examination.

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 9-11 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Specifically, the claims encompass a polyolefin dispersion containing acidic groups which are stabilized by an amine, wherein the acidic group are carboxylic groups and the amine is ammonia.

The specification provides an adequate written description of polyolefins. However, the description of the compounds encompassed by claims 9-11 is vague and no examples of such polymers are provided. The specification fails to inform the reader as to the disposition of the acidic groups in the polymer (e.g. in the chain or as pendant groups) or what the nature of the stabilization is. Is the amine ammonia intended to be a salt? Thus, the polymers encompassed by claims 9-11 are vaguely described and the specification as filed clearly does not provide a representative sample of the polymers encompassed by the claims, given the huge variation in physical, structural, and chemical properties encompassed by the current broad claim language. Because the claims encompass a multitude of polymers neither contemplated nor disclosed by the as-filed disclosure, it is clear that applicant was not in possession of the full scope of the claimed subject matter at the time of filing.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2, 4, 7, 9-11, and 13-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 2, 4, 7, and 20-24 are rejected because they contain claim limitations that are enclosed by parentheses. The use of parenthetical expressions renders the claims indefinite because it is unclear whether the limitation(s) enclosed by the parentheses are part of the claimed invention.

Claims 4 is rejected because the phrase "has a melting traject ending at a temperature ranging from 100 to 200 degrees C" is confusing. It is unclear how a value can end in a given range. It is suggested that "traject" be changed to "trajectory".

Claims 9-11 are rejected because the position/connection of the acidic groups in the polyolefin are unclear. Are the acidic groups pendant or attached to the chain? What is the nature of the stabilization by the amine?

Claim 13 is rejected because the phrase "comprising utilizing" renders the claim vague.

Claims 18 and 19 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: actual physical steps that define the nature of the utilization. The use of the term "utilizing" fails to define any positive method steps.

Claims 14-17 are dependent claims that do not overcome the deficiencies of the independent claim that they are dependent therefrom.

*Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 2, 5, 6, 8-21, 25 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Itoh et al. (US 5,080,917; cited in the IDS filed 11/15/06) in view of Thoma et al. (1999).

Itoh et al. disclose coated granules for animal feed and a method of making said granules. The core can comprise a starch and an active substance that can be an enzyme such as a protease (col. 2, lines 44-50), as in claims 1, 12-19 and 26, in part. Other constituents include amino acids and vitamins. The enzyme-core granulate is prepared by conventional means which include granulating, drying and making the granule in a spherical shape (col. 4, lines 15-55), as in claim 15. The coating agent comprises copolymers formed from alkyl esters of methacrylic acid and dimethylaminoethyl methacrylate such as Eudragit E100 (Butyl methacrylate-2-(dimethylamino)ethyl methacrylate-

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methyl methacrylate polymer). This disclosure meets in part, the limitations of claims 9-11. Despite the vagueness and lack of written description in the specification, claims 9-11 are interpreted to mean that the polyolefin is derivatized by adding a pendant chain having a carboxy group which is made into a salt by the presence of a quaternary amine. In effect, the limitations of claim 9-11 are interpreted to mean a polymer of (meth)acrylic acid ammonium salt. The disclosure by Itoh et al. meets these limitations in part, because Eudragit contains methacrylate monomers that are interpreted to meet the limitation of claims 9 and 10 for the reasons stated. Itoh et al. disclose that these polymeric coatings are water soluble and can be applied by a spraying method as an aqueous solution to the granules (col. 4, lines 55-64), as in claims 5 and 6. The polymer coating can be applied to the granule individually or with an additive such as ethyl cellulose (col. 3, lines 35-40). It is noted that the language of the instant claims is open and that the claimed coatings can comprise other substances. The ratio of the coating to the granule core is at a weight ratio of 5 parts per 100 parts core (col. 4, lines 30-40). Thus, in a coated granule, the percent weight ratio is about 2.5 to 50%, which overlaps the range of claims 2, 8, 20, 21 and 25.

Itoh et al. do not teach that the polyolefin derivative is a (meth)acrylate that is stabilized by an ammonia.

Thoma et al. disclose a comparison of the stability of a range of enteric polymer coatings on enzyme-containing granules and tablets containing vitamin B12. The polymers included an aqueous dispersion of methacrylic/acrylate copolymers (Eudragit L 100-155 and Eudragit L 30D55) with and without ammonia. Thoma et al. report that the Eudragit polymers were coated onto the pills containing B12. The Eudragit polymers maintained their stability and gastrointestinal protective ability after long term storage under various conditions of temperature and humidity. A coating

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comprising the Eudragit polymers with ammonia had the same effect as a coating having a Eudragit polymer lacking ammonia (Figure 1, page 41).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ Eudragit polymers with or without ammonia as a coating for the enzyme-containing granulates of Itoh. The ordinary artisan would have been motivated to do so because the purpose of the coatings of Itoh and Thoma is the same: to protect the biologically active substance from the environment while in storage and the gastrointestinal acid of the stomach on first pass. The ordinary artisan would have realized that methacrylic co-polymers such as Eudragit polymers are effective at accomplishing both aims. The ordinary artisan would have realized from Thoma that the addition of ammonia is a matter of design choice as it does not have a deleterious effect on the stability of the Eudragit polymers.

Claim 3 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Hanley whose telephone number is 571-272-2508. The examiner can normally be reached on M-F 9:00-5:30.

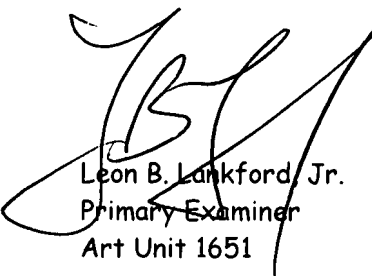


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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Susan Hanley  
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